

APPLICATION GUIDE FOR BROAD MEDICAL LICENSE

A review of the North Carolina Regulations for Protection Against Radiation 15A NCAC 11 must be done with particular consideration to the section that is applicable to the license you are applying for and section .1600, Standards for Protection Against Radiation. Items that need to be addressed in section .1600 include:

- a) .1603 Radiation Protection Program
- b) .1604 Occupational Dose Limits for Adults, including establishment of investigational limits.
- c) .1610 Dose to an Embryo/fetus
- d) .1611 Dose Limits for Individual Members of the Public
- e) .1627 Procedures for Receiving and Opening Packages

All of these items need to be addressed in the form of a policy or procedure. These policies and procedures must be written according to the regulations, so you must review each area before you write your policy or procedure.

1. Fill out the enclosed Application for Radioactive Material License form completely. Use attachments when necessary. ***This form must be signed and dated by one of the highest ranking University/Hospital officials.*** Please state who may sign for future amendments in the form of a memorandum from the president.

- Item 1 a- State name and mailing address. This is the mailing address and should include the nine digit Zip Code.
- Item 1 b- Provide telephone number and extension if applicable.
- Item 1 c- Provide facsimile number.
- Item 1 d- This is the physical address at which radioactive materials will be used (DO NOT LIST A P.O. BOX HERE).
- Item 2- Please indicate what departments will be using radioactive material.
- Item 3- Please indicate current license number or if you are applying for a new license, please state.
- Item 4- Please indicate the Radiation Safety Committee will approve all users of radioactive material.
- Item 5- Indicate who will serve as the Radiation Safety Officer.

NOTE: The information referenced in Items 6 through 15 should be included as attachments to the application

- Item 6 a- Please list all isotopes that will be used. Atomic numbers 1-83 need not be listed, but please request. All other isotopes must be listed separately.
- Item 6 b- List the chemical or physical form of the radioactive material you have requested and the maximum amount you plan to possess.
- Item 7- Describe all uses the radioactive material will be used for.
- Item 8&9- Please submit policy on how authorized users are approved by the Radiation Safety Committee.
- Item 10- All survey meters must be listed.
- Item 11- Indicate all information concerning the calibration of the survey meters and who will calibrate them. If calibrations will be done by the radiation safety office, please submit calibration policy and procedure.
- Item 12- Indicate what types of dosimetry you will be using and who your supplier will be. If bioassays will be performed, please submit the policy regarding necessity and frequency.
- Item 13- Indicate which attachment is the sketch of the facility or facilities. Indicate where the hoods, sinks, work areas and shielding is located. If you have a hood, indicate

- the face velocity, and frequency of calibration.
- Item 14- This is to be incorporated into the radiation protection program already discussed on page one. Please enclose all information about leak testing sealed sources under an attachment and indicate here. If leak tests will be done by the radiation safety office, please submit leak test procedure.
- Item 15- If you hold waste on site, please submit your procedure to assure the waste is at background radiation levels before disposal. Waste must be held for 10 half lives and radiation levels must be at background before disposal if held for decay. All labels must be defaced or removed before disposal. Please indicate on the sketch of your facility where the storage area of waste for decay is located. If a commercial disposal company is used, please state name and address.
- Item 16- ***The application must be dated and signed by the highest ranking University/Hospital official for your department (e.g., President, Chancellor, Vice Chancellor, etc.).*** Mail the entire application packet to Chief, Radioactive Materials Section, Division of Radiation Protection, 3825 Barrett Drive, Raleigh, NC 27609-7221. ***Be sure to retain a copy for your records. If the form is not signed, the application will be mailed back to you.***
2. Submit samples of forms used for receipt, use, disposal and physical inventory of sealed sources of radioactive materials.
 3. Submit procedures for the following areas:
 - a) Emergency procedure for spills and accidents.
 - b) Surveys of use areas. Equipment that will be used to count the samples, frequency of the surveys and level of contamination that will require clean-up and re-survey.
 - c) Describe how records will be maintained of receipt, use and disposal of radioactive materials to assure the possession limit will not be exceeded.
 - d) Proper clothing is worn and safety rules are followed by personnel while in the labs.
 4. Describe security of labs when not in use and training of auxiliary personnel in regard to the hazards of radiation.
 5. Fill out the enclosed form-Memorandum To All Licensees. 15A NCAC 11.0324 (b) discusses requirements for the Radiation Safety Committee. These requirements must be fulfilled. Please also include the frequency this Committee will meet and their responsibilities. This committee should oversee the approval of all procedures done, keep minutes of meetings and be responsible for the radiation safety program.
 6. 15A NCAC 11.0324 (a)(2) & (a)(2)(C) describe safety evaluations that must be conducted by the Radiation Safety Office. Please describe what type of evaluations/inspections are done of all labs that use radioactive material. Please describe the enforcement policy that is used for inspections once a problem has been found. Indicate at what frequency inspections are done.
 7. Address how authorized users will be approved by the Radiation Safety Committee. Include what qualifications must be met before they are approved for use. Indicate what records will be maintained of this individual's education, training and experience.
 8. Address how new uses of radioactive material and isotopes included under 1-83 will be approved by the Radiation Safety Committee. Indicate what records will be maintained for these new uses.
 9. Describe what type of training will be done for employees in the labs and clinical areas who will be supervised by the authorized user. If a test is given by the radiation safety office, please submit a copy of the test and the minimum score allowed for passing. Discuss refresher training (frequency, content, etc.)

10. Describe in detail receipt procedures for all radioactive material. How is the material transported to each lab and what records are maintained in each lab?
11. Describe in detail all waste handling. How often is waste picked up in each lab? How is solid/liquid waste, animal carcasses, etc. disposed of? What records for waste are maintained by the lab and the radiation safety office?
12. How often are authorized user protocols reviewed? How is a protocol amended to increase possession limit or add a new isotope?
13. Submit a copy of the radiation safety manual for research and clinical authorized users.
14. Review 15A NCAC 11 .0353 & .0354 concerning financial assurance for decommissioning. If the calculations demonstrate that no financial assurance is necessary, simply state in the application that it is not required. If some form of surety is necessary, contact the Radioactive Materials Section and ask to speak with a health physicist. They will be able to assist you in this process.
15. Submit the following information:
 - a) Quality Management Program (to include information on written directives)
 - b) Misadministration policies and procedures (including accelerator and sealed source usage where applicable);
 - c) Policies addressing 15A NCAC 11 .0358 concerning release of patients containing radioactive materials and/or permanent implants;
 - d) Policies and procedures to address 15A NCAC 11 .0359 (Measurements of unsealed radioactive materials) .0360 (surveys for contamination and exposure rate) and .0361 (medical use of unsealed radioactive material)
16. Provide policies/procedures on how clinical trials and medical research protocols will be approved by the IRB and RSC.
17. Submit policies/procedures for the following (where applicable):
 - a) HDR (source changeouts, QA, instrumentation, interlocks, leak tests, etc.)
 - b) Brachytherapy (15A NCAC 11 .0702)
 - c) Blood Irradiator(s) and/or Pathology Laboratory use of radioactive materials.
18. All applicants for a Radioactive Materials License must provide documentation from the N.C. Secretary of State which indicates their legal business name in North Carolina. Other forms of this documentation may be acceptable to the agency. If you have questions, call the Radioactive Materials Branch for assistance.

Additional information is being compiled for inclusion in our website. Please visit the site often to check for the most up-to-date information (www.drp.enr.state.nc.us).